§520.2220c

per day until the animal is free of symptoms for 48 hours.

- (ii) *Indications for use*. Treatment of sulfadimethoxine-susceptible bacterial infections.
- (iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (3) Beef cattle and nonlactating dairy cattle—(i) Amount. Administer one 12.5-gram-sustained-release bolus for the nearest 200 pounds of body weight, i.e., 62.5 milligrams per pound of body weight. Do not repeat treatment for 7 days.
- (ii) Indications for use. Treatment of shipping fever complex and bacterial pneumonia associated with organisms such as Pasteurella spp. sensitive to sulfadimethoxine; calf diphtheria and foot rot associated with Fusobacterium necrophorum sensitive to sulfadimethoxine.
- (iii) Limitations. Do not use in female dairy cattle 20 months of age or older. Do not administer within 12 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 43488, Sept. 22, 1975; 49 FR 36830, Sept. 20, 1984; 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997; 64 FR 15684, Apr. 1, 1999; 70 FR 16934, Apr. 4, 2005; 76 FR 17337, Mar. 29, 2011]

\$520.2220c Sulfadimethoxine oral suspension.

- (a) *Chemical name*. N'-(2,6-Dimethoxy-4-pyrimidinyl) sulfanilamide.
- (b) Specifications. Each milliliter of the drug contains 50 milligrams of sulfadimethoxine.
- (c) Sponsor. See Nos. 000061 and 000069 in $\S510.600$ (c) of this chapter.
- (1) It is intended for use in the treatment of sulfonamide susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.
- (2) On the first day of treatment administer an oral dose of 25 milligrams per pound of body weight, then follow with a daily dosage of 12.5 milligrams per pound of body weight. Length of treatment will depend upon clinical response. Continue treatment until patient is asymptomatic for 48 hours.

Maintain adequate water intake during the treatment period.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2220d Sulfadimethoxineormetoprim tablets.

- (a) Specifications. Each tablet contains 120 milligrams (100 milligrams of sulfadimethoxine and 20 milligrams of ormetoprim), 240 milligrams (200 milligrams of sulfadimethoxine and 40 milligrams of ormetoprim), 600 milligrams (500 milligrams of sulfadimethoxine and 100 milligrams of ormetoprim), or 1200 milligrams (1,000 milligrams of sulfadimethoxine and 200 milligrams of ormetoprim).
- (b) *Sponsor*. See No. 000069 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. On the first day of treatment, administer 25 milligrams per pound (55 milligrams per kilogram) of body weight. Then follow with a daily dosage of 12.5 milligrams per pound (27.5 milligrams per kilogram) of body weight.
- (2) Indications of use. Treatment of skin and soft tissue infections (wounds and abscesses) in dogs caused by strains of Staphylococcus aureus and Escherichia coli and urinary tract infections caused by Escherichia coli, staphlococcus spp., and Proteus mirabilus susceptible to ormetoprim-potentiated sulfadimethoxine.
- (3) Limitations. Continue treatment until patient is asymptomatic for 48 hours, but do not exceed a total of 21 consecutive days. Maintain adequate water intake during the treatment period. Safety in breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 48593, Nov. 24, 1989, as amended at 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 61 FR 46719, Sept. 5, 1996]

§ 520.2240 Sulfaethoxypyridazine.

§ 520.2240a Sulfaethoxypyridazine drinking water.

(a) Chemical name. N'-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

Food and Drug Administration, HHS

- (b) Specifications. Melting point range of 180 $^{\circ}\mathrm{C}.$ to 186 $^{\circ}\mathrm{C}.$
- (c) *Sponsor*. See No. 053501 in §510.600(c) of this chapter.
- (d) Related tolerances. See §556.650 of this chapter.
- (e) Conditions of use. It is used as follows:
- (1) Swine—(i) Amount. 1.9 to 3.8 grams per gallon (0.05 percent to 0.1 percent).
- (ii) *Indications for use*. Treatment of bacterial scours pneumonia enteritis, bronchitis, septicemia accompanying *Salmonella cholerasuis* infection.
- (iii) Limitations. Administer 3.8 grams per gallon for first day followed by 1.9 grams per gallon for not less than 3 days nor more than 9 days as sodium sulfaethoxypyridazine; do not treat within 10 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian.
- (2) Cattle—(i) Amount. 2.5 grams per gallon (0.066 percent).
- (ii) Indications for use. Treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.
- (iii) Limitations. Administer at the rate of 1 gallon per 100 pounds of body weight per day for 4 days; as sodium sulfaethoxypyridazine; do not treat within 16 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food.

[40 FR 13838, Mar. 27, 1975, as amended at 67 FR 78355, Dec. 24, 2002]

§ 520.2240b Sulfaethoxypyridazine tablets.

- (a) Chemical name. N'-(6-Ethoxy-3-pyridazinyl) sulfanilamide.
- (b) Specifications. Melting point range of 180 $^{\circ}\mathrm{C}$ to 186 $^{\circ}\mathrm{C}.$
- (c) Sponsor. See No. 053501 in §510.600(c) of this chapter.
- (d) Related tolerances. See §556.650 of this chapter.
- (e) Conditions of use. It is used for cattle as follows:
- tle as follows:
 (1) Amount. 2.5 or 15 grams per tablet.
- (1) Amount. 2.5 or 15 grams per tablet. (i) Indications for use. Treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as

- adjunctive therapy in septicemia accompanying mastitis and metritis.
- (ii) Limitations. Administer 25 milligrams per pound of animal weight per day for 4 days; do not treat within 16 days of slaughter; as sole source of sulfonamide; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food; for use only by or on the order of a licensed veterinarian.
- (2) Amount. 15-gram controlled release tablets.
- (i) Indications for use. Treatment of foot rot and respiratory infections (shipping fever and pneumonia) caused by sulfonamide-susceptible pathogens (E. coli, streptococci, staphylococci, Sphaerophorus necrophorus and Gramnegative rods including Pasteurella); for use prophylactically in cattle during periods of stress for reducing losses due to sulfonamide sensitive disease conditions
- (ii) Limitations. Administer 100 milligrams per pound of body weight; do not treat within 16 days of slaughter; as sole source of sulfonamide; not for use in lactating dairy cows; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 67 FR 78355, Dec. 24, 2002]

§ 520.2260 Sulfamethazine oral dosage forms.

§ 520.2260a Sulfamethazine oblet, tablet, and bolus.

- (a)(1) Sponsor. See No. 000010 in §510.600(c) of this chapter for use of 2.5-, 5-, and 15-gram sulfamethazine oblet in beef cattle, nonlactating dairy cattle, and horses. See No. 061690 in §510.600(c) of this chapter for use of 5-, 15-, and 25-gram tablet in beef and nonlactating dairy cattle.
- (2) Related tolerance in edible products. See § 556.670 of this chapter.
- (3) Conditions of use—(i) Amount. Administer as a single dose 100 milligrams of sulfamethazine per pound of body weight the first day and 50 milligrams per pound of body weight on each following day.
- (ii) *Indications for use*. For treatment of diseases caused by organisms susceptible to sulfamethazine.